

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

***APPLICATION NUMBER:***

**21-061/SE2-007**

**21-062/SE2-008**

**APPROVAL LETTER**



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 20857

NDA 21-061/S-007  
NDA 21-062/S-008

Bristol-Myers Squibb Company  
Attention: Joan C. Fung-Tomc, Ph.D.  
5 Research Parkway  
Wallingford, CT 06492

Dear Dr. Fung-Tomc:

Please refer to your supplemental new drug applications dated December 21, 2000 and January 2, 2001, received December 21, 2000 and January 3, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Tequin (gatifloxacin) Tablets, 200 and 400 mg, and for Tequin (gatifloxacin) for Injection, 200 and 400 mg, respectively.

We acknowledge receipt of your submissions dated:

|                             |               |                                    |
|-----------------------------|---------------|------------------------------------|
| February 26, 2001           | May 23, 2001  | October 2, 2001 (2 for NDA 21-061) |
| March 7, 2001               | May 24, 2001  | October 9, 2001 (NDA 21-061)       |
| March 28, 2001              | June 1, 2001  |                                    |
| April 18, 2001 (NDA 21-061) | June 26, 2001 |                                    |

These supplemental new drug applications provide for a change in the dosing regimen for the treatment of acute exacerbation of chronic bronchitis (AECB) to five (5) days duration.

We have completed the review of these supplemental applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the agreed upon labeling text. Accordingly, these supplemental applications are approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert submitted May 24, 2001). In addition, all previous revisions as reflected in the most recently approved package insert (NDA 21-061/S-005, NDA 21-061/S-006, NDA 21-062/S-006, and NDA 21-062/S-007 approved August 20, 2001) must be included.

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL to each supplement as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, these submissions should be designated "FPL for approved supplements NDA 21-061/S-005, NDA 21-061/S-006, NDA 21-061/S-007, NDA 21-062/S-006, NDA 21-062/S-007, and NDA 21-062/S-008." Approval of these submissions by FDA is not required before the labeling is used.

As of April 1, 1999, all applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred (63 FR 66632). We are waiving the pediatric study requirement for this action on these applications as this indication (AECB) is not applicable in the pediatric population.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this new regimen for AECB. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, Maryland 20857

If a letter communicating important information about these drug products (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to these NDAs and a copy to the following address:

MEDWATCH, HF-2  
FDA  
5600 Fishers Lane  
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Diana Willard, Regulatory Project Manager, at (301) 827-2127.

Sincerely,

*{See appended electronic signature page}*

Renata Albrecht, M.D.  
Acting Director  
Division of Special Pathogen and Immunologic Drug Products  
Office of Drug Evaluation IV  
Center for Drug Evaluation and Research

Enclosure